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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---------------------------------------|---------------|----------------------|----------------------|------------------|
| 10/701,883 | 11/05/2003 | Nabil L. Muhanna | M112 1071.I | 6707 |
| 26158 | 7590 | 04/28/2011 | | EXAMINER |
| WOMBLE CARLYLE SANDRIDGE & RICE, PLLC | | | PRONE, CHRISTOPHER D | |
| ATTN: IP DOCKETING | | | ART UNIT | PAPER NUMBER |
| P.O. BOX 7037 | | | | 3738 |
| ATLANTA, GA 30357-0037 | | | | |
| MAIL DATE | DELIVERY MODE | | | |
| 04/28/2011 | PAPER | | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|---|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/701,883 | MUHANNA ET AL. | |
| | Examiner CHRISTOPHER D. PRONE | Art Unit 3738 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 08 March 2011.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-4,6-13,15,16,18,20-23,26-30,41-45 and 48-52 is/are pending in the application.
 - 4a) Of the above claim(s) 3,11-13,16,22,23,27-30 and 41-45 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1,2,4,6-10,15,18,20,21,26 and 48-52 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All
 - b) Some
 - c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-922)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) Interview Summary (PTC-413)
Paper No(s)/Mail Date _____
- 5) Notice of Informal Patent Application
- 6) Other: _____

DETAILED ACTION

Status of Claims

Claims 1-4, 6-13, 15, 16, 18, 20-23, 26-30, 41-45, and 48-52 are pending.

Claims 3, 11-13, 16, 22, 23, 27-30, and 41-45 have been withdrawn.

Claims 1, 2, 4, 6-10, 15, 18, 20, 21, 26, and 48-52 stand rejected.

Priority Date

The earliest support for the elected embodiment of this application is in provisional application 60476075 filed on 06/05/03.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

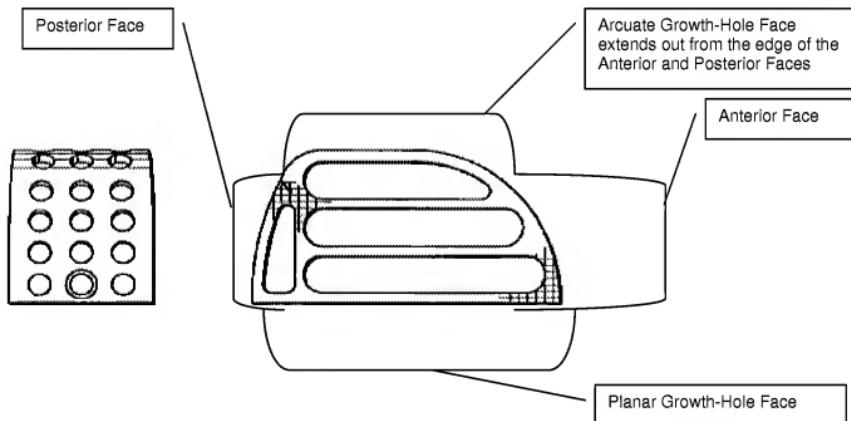
(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 1, 2, 4, 6-10, 15, 18, 20, and 50-52 is rejected under 35 U.S.C. 103 as being unpatentable over Michelson United States Patent 6,890,355 in view of Michelson United States Patent 5,609,635 (Michelson II), Brantigan United States Patent 5,192,327 and Viart et al United States Patent 6,682,562 B2.

Michelson discloses a metal vertebral body replacement comprising a body 300, nonparallel top and bottom surfaces (shown best in figures 15-17) having a plurality of through holes and continuous grooves 314 and protrusions (5:62-65), two growth hole

faces 310 (planar) and 312 (curved) having 4 through holes 319 and a curves anterior face 304. Michelson further discloses use of a second identical implant for insertion along side the first 300".

In response to the amended language a marked up figure is included below to demonstrate how the arcuate growth-hole face extends outward.



In regards to claim 2 the grooves on the top surface extend completely through a portion of the top surface.

In regards to claims 48-50 Michelson discloses a plurality of grooves that extend perpendicular to the posterior surface. The first groove on the top is clearly not aligned in the same plane as with the last groove on the bottom.

However Michelson fails to disclose that the top and bottom surfaces are convex and non-planar, a groove on the top surface that extends through the anterior and posterior faces, and teeth aligned generally orthogonal to the grooves.

Michelson II discloses a plurality of vertebral implants comprising top and bottom surfaces that are either planar or convex in the same field of endeavor for the purpose of treating spinal lordosis (1:57-61). Michelson II further discloses that the convex surfaces enable the implant to better conform to the shape of the adjacent vertebral surfaces (2:23-37).

Brantigan discloses a spinal implant comprising a body having a top surface with projections and grooves that extend generally along the top surface of an implant extending through the anterior and posterior faces in the same field of endeavor for the purpose of providing the maximum surface contact thereby securing the implant to the implant site.

Viart discloses a plurality of spinal implant comprising a body having a top surface with varying projections and grooves that are made up of a plurality of teeth aligned with an edge orthogonal to the grooves formed between them in the same field of endeavor for the purpose of providing more distinct contact points (teeth) engaging the surrounding implant site

It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the top and bottom surfaces convex as disclosed in Michelson's earlier patent (Michelson II) in order to better conform to the shape of the adjacent vertebral surfaces.

Additionally, in view of Michelson's lack of specific disclosure for its textured upper surface it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide continuous grooves and protrusions on the top surface as taught by Brantigan and to form the protrusions out of a plurality of teeth with edges aligned orthogonal to the grooves as taught by Viart with the device of Michelson in order to provide an implant with continuous grooves and protrusions having increased contact with the surrounding body that extend through the anterior and posterior surfaces which will secure the implant to the implant site.

In regards to the amended language requiring grooves with width capable of receiving an insertion tool, this is being considered language of intended use. This application is directed at an implant not a tool or a kit for inserting an implant. In view of this and the infinite number of tools that could be used to grasp the implant, it is obvious that the width of the grooves of the modified implant above would be able to be gripped by an insertion tool.

Claim 21 is rejected under 35 U.S.C. 103 as being unpatentable over Michelson in view of Michelson II, Brantigan, and Viart as applied to claims 1, 2, 4, 6-10, 15, 18, 20, and 48-50 above and further in view of United States Patent Paul et al 6,143,033.

The combination of Michelson, Michelson II, Brantigan, and Viart discloses the invention substantially as claimed being described supra. However, combination fails to disclose making his device from the bone comprising the medullary cavity.

Paul teaches the use of an implant made from bone comprising medullary cavity in the same field of endeavor for the purpose of using natural materials that the body will accept and grow into.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine the bone material taught by Paul with the device of Michelson as modified by Brantigan and Viart in order to provide an implant made from all natural materials.

Claim 26 is rejected under 35 U.S.C. 103 as being unpatentable over Michelson in view of Michelson II, Brantigan and Viart as applied to claims 1, 2, 4, 6-10, 15, 18, 20, and 48-50 above and further in view of Wagner et al. United States Patent 5,306,309.

The combination of Michelson, Michelson II, Brantigan, and Viart discloses the invention substantially as claimed being described above. However, the combination fails to disclose making his device from a plurality of bonded layers.

Wagner teaches the use of an implant comprising a base metal having layers bonded to its outer surface in the same field of endeavor for the purpose enhancing the implants material properties. (6:13-40)

It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the implant of Michelson as modified by Brantigan and Viart out of a plurality of layers as taught by Wagner in order to provide an implant with enhanced durability or porosity.

Claims 48 and 49 are rejected under 35 U.S.C. 103 as being unpatentable over Michelson United States Patent 6,890,355 in view of Michelson United States Patent 5,609,635 (Michelson II) and Brantigan United States Patent 5,192,327

Michelson discloses a metal vertebral body replacement comprising a body 300, nonparallel top and bottom surfaces (shown best in figure 17) having a plurality of through holes and continuous grooves 314 and protrusions (5:62-65), two growth hole faces 310 (planar) and 312 (curved) having 4 through holes 319 and a curves anterior face 304. Michelson further discloses use of a second identical implant for insertion along side the first 300".

In regards to claim 2 the grooves on the top surface extend completely through a portion of the top surface.

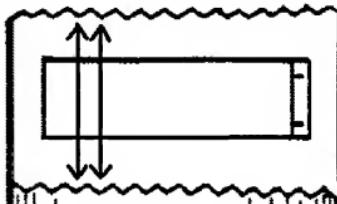
In regards to claims 48-50 Michelson discloses a plurality of grooves that extend perpendicular to the posterior surface. The first groove on the top is clearly not aligned in the same plane as with the last groove on the bottom.

However Michelson fails to disclose the convex top and bottom surfaces that are non-planar, a groove on the top surface that extends through the anterior and posterior faces, and that the grooves on the upper surface are unaligned with the grooves on the lower surface.

Michelson II discloses a plurality of vertebral implants comprising top and bottom surfaces that are either planar or convex in the same field of endeavor for the purpose of treating spinal lordosis (1:57-61). Michelson II further discloses that the convex

surfaces enable the implant to better conform to the shape of the adjacent vertebral surfaces (2:23-37).

Brantigan discloses a spinal implant comprising a body having a top surface with projections and grooves that extend generally along the top through the anterior and posterior faces wherein the projections and grooves are unaligned (see figure below) in the same field of endeavor for the purpose of securing the implant to the implant site.



It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the top and bottom surfaces convex as disclosed in Michelson's earlier patent (Michelson II) in order to better conform to the shape of the adjacent vertebral surfaces.

Additionally, in view of Michelson's lack of specific disclosure for its textured upper surface it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide continuous grooves and protrusions on the top surface that are orientated opposite the grooves and protrusions on the bottom surface as taught by Brantigan with the device of Michelson in order to provide an implant with continuous grooves and protrusions having increased contact with the surrounding body better securing the implant to the implant site.

In response to the amended language requiring the arcuate growth-hole face to extend outward and the grooves to comprise a width capable of receiving an insertion tool, this has been addressed above in the other Michelson combination.

Response to Arguments

Applicant's arguments with respect to all claims have been considered but are moot in view of the new ground(s) of rejection. The applicant's arguments that Michelson fails to disclose convex top and bottom surfaces is not persuasive because Michelson in an earlier patent discloses that the planar and convex surfaces are known to be interchangeable within the art.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTOPHER D. PRONE whose telephone number is (571) 272-6085. The examiner can normally be reached on Monday through Fri 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Christopher D Prone
Examiner
Art Unit 3738

/Christopher D Prone/

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/CORRINE M MCDERMOTT/

Supervisory Patent Examiner, Art Unit 3738